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UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

IN RE RIDDELL CONCUSSION REDUCTION LITIGATION

Civil Action No. 13-7585 (JBS)(JS)

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE TESTIMONY OF ROBERT CANTU

Confidential

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Defendants Riddell, Inc., Riddell Sports Group, Inc., Easton-Bell Sports, LLC, EB Sports Corp., and RBG Holdings Corp. (collectively, the "Defendants") respectfully submit this memorandum in support of their motion to exclude the Expert Report of Dr. Robert Cantu, (Cecchi Decl., Ex. 29) (the "Report") and the deposition testimony of Dr. Cantu dated January 11, 2017 (Declaration of James B. Saylor dated February 9, 2017, the "Saylor Decl.", Ex. 15).

PRELIMINARY STATEMENT

Dr. Cantu's opinion is neither reliable nor relevant. The essence of Dr. Cantu's opinion is that while football helmets do reduce the instances of concussions, the exact measurement of the threshold for a concussion is not known and the instances of concussions cannot be precisely measured. Dr. Cantu requires that a perfect system exist to diagnose concussions and precisely measure concussion reduction before *any* attempts be made to make safer helmets available to the public. This opinion is not helpful to the fact finder because it does not attempt to answer the question of whether Riddell's concussion reduction claims are wrong, understated, or overstated. Indeed, Dr. Cantu, despite his 60 years of experience, does not know whether Riddell's claims are true or false (and, according to him, nobody could know that).

Dr. Cantu's opinion confirms that he is not addressing the question at hand. It is therefore irrelevant. His opinion is also not reliable because his process is not objective, rendering his conclusions subjective and ephemeral. Dr. Cantu's method for surveying the universe of literature is undefined; the universe of literature is undefined; the basis for reaching his conclusions is undefined; and the question of what constitutes support in the medical scientific literature is based solely on Dr. Cantu's ill-defined and subjective view.

Pending before the Court is Plaintiff's Motion for Class Certification, as well as Defendants' four *Daubert* motions to exclude the testimony of Plaintiff's experts. Defendant request that the *Daubert* motions be decided prior to the Motion for Class certification. *See In re Blood Reagents Antitrust Litig.*, 783 F.3d 183, 187 (3d Cir. 2015).

Dr. Cantu disregards two studies that directly refute his claim that one helmet's efficacy cannot be measured against another: the UPMC Study and the Virginia Tech Study. He relies on two other studies that he claims refute the UPMC Study: the Wisconsin Study and the 2016 study by Dr. Christy Collins. The Wisconsin Study does not contradict the UPMC Study, as the Court already found. Saylor Decl., Exs. 28 and 29, Dkt No. 65 at 29-30. The Collins Study does not even attempt to measure the rates of concussions by helmet maker or model. Thus, Dr. Cantu's own opinion persists despite the fact that, as he admits, he is basing it on no direct evidence supporting Riddell, no direct evidence contradicting Riddell and no evidence supporting his opinion (other than his say so).

Here, Riddell is not challenging Dr. Cantu's qualifications, but because his methodology is unreliable and his opinion is not relevant, his opinion should be excluded by the Court. His proposed testimony is irrelevant and inadmissible because his methodology does not "fit" with plaintiffs' theory of liability and will not help the trier of fact to understand the evidence or determine a fact in issue.

LEGAL STANDARD

The admissibility of expert testimony is governed by Federal Rule of Evidence 702 ("Rule 702") and the Supreme Court's opinion in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 113 S. Ct. 2786 (1993). *See Neale v. Volvo Cars of N. Am., LLC*, No. 2:10-cv-4407 (DMC)(MF), 2013 WL 784962 at *1 (D.N.J. Mar. 1, 2013). Rule 702 permits a qualified witness "to testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case." *Id.* at *2 (citing Rule 702). Rule 702's three

basic requirements for expert testimony to be admitted are: (1) the evidence must be useful to a finder of fact; (2) the witness must be qualified to provide the testimony; and (3) the proposed evidence must be reliable or trustworthy. *See In Re ConAgra Foods, Inc.*, 302 F.R.D. 537, 549 (C.D. Cal. 2014). The burden is on the proponent of the evidence to show, by a preponderance of the evidence, that Rule 702 is satisfied. *See Daubert*, 509 U.S. at 592, n.10; *In re ConAgra*, 302 F.R.D. at 549; *see also Oddi v. Ford Motor Co.*, 234 F.3d 136, 144 (3d Cir. 2000).

In the Third Circuit, expert testimony used to support class certification must comply with *Daubert. In re Blood Reagents Antitrust Litig.*, 783 F.3d 183, 187 (3d Cir. 2015) ("[A] plaintiff cannot rely on challenged expert testimony, when critical to class certification, to demonstrate conformity with Rule 23 unless plaintiff also demonstrates, and the trial court finds, that the expert testimony satisfies the standard set out in Daubert."); *see also In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 323 (3d Cir. 2008) ("Expert opinion with respect to class certification like any matter relevant to a Rule 23 requirement, calls for rigorous analysis. It follows that opinion testimony should not be uncritically accepted as establishing a Rule 23 requirement . . ."). A recent decision from the Eastern District of Pennsylvania barred Plaintiffs' damages expert in this case (Charles D. Cowan) under *Daubert*, and then denied class certification. *In re Pharmacy Benefit Managers Antitrust Litig.*, 2017 WL 275398 (E.D. Pa. Jan. 18, 2017).

Rule 702 "affirms the trial court's role as gatekeeper and provides some general standards that the trial court must use to assess the reliability and helpfulness of proffered expert testimony." *Calhoun v. Yamaha Motor Corp.*, 350 F.3d 316, 321 n.9 (3d Cir. 2003) (internal quotations omitted). Rule 702 requires that the expert testimony help the trier of fact to understand the evidence or to determine a fact in issue. *Neale*, 2013 WL 784962 at *3 (granting

the plaintiff's motion to exclude defendant's proffered expert opinion because it found it "speculative and without foundation.") "The *Daubert* standard requires [that . . .] expert testimony is grounded in methods and procedures of science, [and that it] provides more than a subjective belief or unsupported speculation, and be not only relevant but reliable." *Neale*, 2013 WL 784962, at *2 (quoting *Daubert*, 509 U.S. at 589). If the expert's testimony is irrelevant or unreliable, it will not help the trier of fact to determine a fact in issue and it should be excluded.

The Courts should avoid a "battle of the experts" and exclude any expert whose testimony is not qualified, not reliable, or not relevant. *See In re Bayer Healthcare and Merial Ltd. Flea Control Prods. Mktg. and Sales Practices Litig.*, 752 F.3d 1065, 1077 (6th Cir. 2014) (plaintiff unable to show that defendant's studies substantiating their claims were unreliable, inaccurate, or not relevant); *see also Jones v. Syntes USA Sales, LLC*, 2010 WL 3311840, at *9-10 (D.N.J. Aug. 19, 2010) (striking an expert for being unqualified, using unreliable methods, and giving irrelevant testimony).

DR. CANTU'S REPORT AND OPINION

Dr. Robert C. Cantu submitted a five page report in support of his testimony in this matter. Cecchi Decl., Ex. 29. The only portions of the report that are responsive to this case are a series of bullet points that are mere conclusions or observations. Some of these Dr. Cantu conceded, under oath during his deposition, were wrong and/or not a basis of his expert opinion. The laundry list of bullet points appears on the second and third pages of his Declaration and are sandwiched between the subsections titled "Introduction" and "Conclusions." *Id*.

In his "Introduction," Dr. Cantu explains that he has been retained to offer an opinion on the Riddell Revolution series of helmets. Cecchi Decl., Ex. 29. He includes a footnote listing 24 types of Riddell football helmets that are within his "understanding" of what the Revolution series includes. *Id.*, at 2. During his deposition, Dr. Cantu admitted that he was not familiar with

those helmets and that he did not draft the footnote in his report. Saylor Decl., Ex. 15 at 64:20-65:9. The remaining sentences in his introduction are really conclusions. Dr. Cantu concludes, based on his knowledge and experience, that he "can affirmatively state that scientifically and medically, not enough is known about the occurrence and mechanisms of concussions to affirmatively represent that one helmet possesses a technology to reduce concussions, particularly, more so than other helmets on the market." Report at 2. He then posits, "[i]n other words, any advertisement that those helmets reduce concussion risk more than other helmets, whether implicit or explicit, has no scientific and medical merit." *Id.* Nowhere in his report or during his deposition did Dr. Cantu set forth a process he applied to reach the conclusions in the "Introduction" section of his report.

In the "Conclusions" subsection of his report, Dr. Cantu explains that he "surveyed the present state of medical literature, documents relevant to this case, and incorporate[ed] [his] over sixty (60) years of experience as a Neurosurgeon, [he] [is] able to make the following conclusions." Report at 2. This cursory explanation is followed by nine bullet points of Dr. Cantu's conclusions. *Id.* No further support is provided to explain how he reached his conclusions. In the section on the fifth page titled "Documents Considered," only two of the nine documents listed are medical studies: the "UPMC Study" and the "Wisconsin Study"; the other seven documents are pleadings, orders, and transcripts from this case. Report at 5.

Dr. Cantu's first conclusion is that, "there is not enough known about the mechanism of concussion to affirmatively state that a helmet can reduce the incident of concussions." Report at 3. This conclusion is wrong and directly contradicted by Dr. Cantu himself. When explaining this odd conclusion at his deposition, Dr. Cantu backpedaled, and said, "I think what I'm really referring to more in that [conclusion] is reduce the concussion when we're dealing with football

or ice hockey type blows where you're dealing primarily with in football head to head or helmet-to-helmet contact. . . . We can't say precisely how much it reduces the concussion even in this instance, but we do believe that it does a better job when the masses are light." Saylor Decl., Ex. 15 at 87:12-24. Thus, Dr. Cantu concedes that football helmets can reduce the incidence of concussion. He further clarifies by admitting his first conclusion is "essentially saying there is not enough known about the mechanism of concussion to affirmatively state *how much* a helmet can reduce the incidence of concussion." *Id.* at 94:17-23 (emphasis added). This sloppy use of language is another befuddling aspect of Dr. Cantu's opinions.

Dr. Cantu's second conclusion is that, "[t]he definition of concussion is widely varied within the scientific community (i.e. there is no single universally used definition of concussion in the medical and/or scientific community)." Report at 3. Once again, Dr. Cantu backpedals from his report by admitting that this conclusion does not have a "dramatic impact" on this case, and admits that the definition of concussion has "minimally changed from 2001 through 2012." Saylor Decl., Ex. 15 at 95:22-25; 99:9-11. Indeed, Dr. Cantu authored a book published in 2012 titled, "Concussions and Our Kids." Saylor Decl., Ex. 17. His intended audience for the book is parents considering contact sports for their children. Saylor Decl., Ex. 15 at 103:19-22. In the book, he gives an even older definition of the meaning of concussion than the one applicable during the relevant time period in this case. *Id.* at 102:7-20.

Next, Dr. Cantu concludes that, "[i]mpact tests performed in laboratories do not equate to clinical reductions in the incidence of concussions on the playing field." Report at 3. Dr. Cantu explained at his deposition that he "essentially" believes there is "no relation between impact tests performed in laboratories today [that he knows] of on football helmets and the clinical reductions in the incidents of concussions on the playing field." Saylor Decl., Ex. 15 at 108:20-

109:4. At his deposition he was shown a publication by the safety setting body for football helmets, the National Operating Committee on Standards in Athletic Equipment ("NOCSAE"). Dr. Cantu is the Vice President of NOCSAE. The NOCSAE publication expressly states that helmets that are "certified to a NOCSAE standard provide[] a substantial level of protection for serious head injuries, including concussions[.]" Saylor Decl., Ex. 16. Thus, this portion of Dr. Cantu's opinion is contradicted by the very committee of which he is a contributor.

Dr. Cantu also makes an exception that his conclusion is not reflective of accelerometer studies. Saylor Decl., Ex. 15 at 110:8-13. This is important because one of the studies that directly tested Concussion Reduction Technology ("CRT") used accelerometers to study the efficacy of CRT. Saylor Decl., Ex. 30. This study is curiously absent from Dr. Cantu's list of "Documents Considered." Report at 5.

Dr. Cantu's next conclusion is that, "[c]oncussion diagnosis is significantly underreported so any available data regarding the frequency and occurrence of concussions suffers from incompleteness and inaccuracy." Report at 3. Dr. Cantu, however, said at his deposition that "there are more concussions being diagnosed today because people are being in general ... more thorough in assessing for a concussion when it's suspected, No. 1. No. 2, not across the board, but in general athletes are being more honest today about reporting concussion symptoms ..." Saylor Decl., Ex. 15 at 113:16-25. He further explains that "[t]he major reason why there are more concussions identified today . . . is better accuracy at recognizing them and so . . . the distant past lack of recognition is what led to the majority of the inaccuracy of the reporting." Saylor Decl., Ex. 15 at 118:6-11. Thus, his opinion supports the notion that increases in concussion rates in football are not due to a failure of helmet technology, but because more concussions are being reported and more symptoms are being included in the diagnosis of

concussion. This part of his opinion directly rebuts an underlying theory in Plaintiffs' falsity claims. Rates of concussions are not on the rise because advancements in helmet safety are illusory. Rather, concussions rates are on the rise, mainly because more are being reported (due to greater recognition and an expanding universe of symptoms being associated with concussion). In fact, Dr. Cantu concedes the value of football helmets when it comes to concussion reduction. Dr. Cantu believes that a "football helmet can reduce the incidence of concussion." Saylor Decl., Ex. 15 at 152:24-153:12.

Dr. Cantu's fifth conclusion is that, "[t]here are not yet reliable tests for determining thresholds for human concussions, particularly in different age groups." Report at 3. Dr. Cantu conceded at his deposition that there is no test at all for determining the threshold for human concussions, and that, in his opinion, it will be "very complicated" to come up with a test to determine the threshold for human concussion because the "threshold is not going to be the same for all people." Saylor Decl., Ex. 15 at 118:16-21; 119:12-17.

Dr. Cantu never explains the import of this opinion to this case. It appears that Dr. Cantu would allow the perfect to be the enemy of the good by requiring a perfect test for concussion thresholds before anyone could claim to measure concussion and try to protect to a reasonable threshold. This is a completely unreasonable outcome and inconsistent with good medicine, reliable science, and common sense. As a medical doctor, Dr. Cantu obviously believes in treating known concussions, as he has written extensively on the topic. Surely, the lack of precise thresholds, or even a definitely or completely comprehensive concussion definition has not stopped his efforts in this regard.

Despite Dr. Cantu's resistance, although an exact threshold may not exist, the UPMC Study showed that CRT decreased rates of concussion over traditional helmets. That fact has

been shown by part of the medical and scientific literature. *See Riddell, Inc. v. Schutt Sports, Inc.*, 724 F. Supp.2d 963, 975 (W.D. Wis. 2010). The Virginia Tech Study further supports that finding and is also part of the scientific and medical literature. Saylor Decl., Ex. 30. There is no study that contradicts it. The Wisconsin Study does not. Saylor Decl., Ex. 29; Dkt. No. 65, at 30. The 2016 Collins Study did not detect rates of concussions by manufacture/model. Saylor Decl., Ex. 19. Dr. Cantu is wrong about the support in the scientific and medical literature for CRT. Such support exists and in fact overwhelming points to the efficacy of CRT.

Dr. Cantu next opines that, "[e]ven if biomechanical studies have shown a reduction in impact forces to the brain with the use of head gear and/or helmets, these findings, as yet, do not translate to show a reduction in concussion incidence." Report at 3. Dr. Cantu offers no explanation to support this subjective claim. He does not even cite to the Virginia Tech study which reaches a different conclusion about the biomechanical aspects of CRT, stating, "[f]rom a biomechanical standpoint, the difference in concussion risk between helmets is logical." Saylor Decl., Ex. 30. The Virginia Tech study concludes that "differences in the ability to reduce concussion risk exist[s] between helmet models in collegiate football. Helmet designs should be optimized to reduce head acceleration over the continuum of impacts experienced by football players. Helmet design may never prevent all concussions from occurring in football, but the evidence illustrates that it can reduce the incidence of this injury." *Id*.

One of Dr. Cantu's boldest conclusions is that "[t]here is no reliable scientific evidence to support greater efficacy of one particular type of football helmet." Report at 3. He explains that when he says "no reliable scientific evidence," he actually means "a consensus in the scientific literature that there either is or there isn't a football helmet that's more protective than another." Saylor Decl., Ex. 15 at 144:17-145:5. It is unclear if Dr. Cantu now finds a lack of "consensus in

the scientific literature" (whatever that means), equates it to "no reliable scientific evidence," or whether it is meant to loosen or tighten his standard. In any event, Dr. Cantu appeared comfortable having his name on a document that claimed a 50% reduction in the incidence of concussions for the helmet of Riddell's competitor Xenith. Saylor Decl., Ex. 74, at RIDDELL-FTC-049727.

Next, Dr. Cantu states that, "[t]he mechanical event that leads to a concussion is not understood well enough to state that a particular helmet can reduce the incidence of concussion." Report at 3. When asked about this conclusion at his deposition, Dr. Cantu's issued yet another retraction testifying: "Well, I could even go without that point." Saylor Decl., Ex. 15 at 150:6-15. Thus, Dr. Cantu appears to concede that there are differences between helmets when it comes to concussion reduction attributes.

Finally, Dr. Cantu concludes that, "[t]he objective, age-specific markers for metrics for diagnosis of the clinical entity that is a concussion are not understood enough to state that a particular helmet can reduce the incidence of concussion to any discernible degree, or in relation to any other helmets on the market." Report at 3. Again, Dr. Cantu indicates that you can disregard this conclusion, but goes on to explain that he means "the diagnosis of concussion is made a lot of different ways. It's not uniform. And so if we're going to talk about reducing incidence or blocking increased incidence, we're going to have to get at a uniform diagnosis." Saylor Decl., Ex. 15 at 153:23-154:1; 154:2-8. Again, Dr. Cantu is willing to await the perfect world of 100 percent agreement on a uniform diagnosis, and preclude the good that comes from protecting players here and now. In short, Dr. Cantu's only true opinion is not that Riddell overstated the ability of its helmets to reduce the incidence of concussion, but merely there is no

way to measure the exact amount which a helmet reduces the incidence of concussion. The relevance of that conclusion to this case is nil.

ARGUMENT

I. DR. CANTU'S TESTIMONY SHOULD BE EXCLUDED BECAUSE IT IS NOT RELIABLE

An expert's opinion "must be based on the methods of science rather than on subjective belief or unsupported speculation." *Calhoun v. Yamaha Motor Corp.*, 350 F.3d 316, 321 (3d Cir. 2003). Although '[t]he evidentiary requirement of reliability is lower than the merits standard of correctness", a litigation must "make more than a *prima facie* showing that his expert's methodology is reliable. *Pineda v. Ford Motor Co.*, 520 F.3d 237, 247 (3d Cir. 2008).

In re Paoli R.R. Yard PCB Litig. set out factors that can be used to assess whether an expert's methodology is reliable:

- (1) whether a method consists of a testable hypothesis;
- (2) whether the method has been subject to peer review;
- (3) the known or potential rate of error;
- (4) the existence and maintenance of standards controlling the technique's operation;
- (5) whether the method is generally accepted;
- (6) the relationship of the technique to methods which have been established to be reliable;
- (7) the qualifications of the expert witness testifying based on the methodology;² and
- (8) the non-judicial uses to which the method has been put.

35 F.3d 717, 742 n.8 (3d Cir. 1994). This list is neither exhaustive nor applicable in every case. *Kannankeril v. Terminix Int'l, Inc.*, 128 F.3d 802, 806-07 (3d Cir. 1997). Determining admissibility of an expert's testimony focuses on the expert's "principles and methodology, not

² Riddell does not contest Dr. Cantu's qualifications, so this factor is intentionally omitted from the discussion below.

on the conclusions that they generate." *Meadows v. Anchor Longwall & Rebuild, Inc.*, 306 Fed. Appx. 781, 789 (3d Cir. 2009) (quoting *Daubert*, 509 U.S. at 595).

A. <u>Dr. Cantu's Method And Hypothesis Is Not Testable</u>

The Rule 702 analysis centers on an expert's methodology, and yet it is striking that Dr. Cantu's methodology is never identified in his report, much less described. Dr. Cantu's methods are purely subjective and untestable by anyone other than him. It appears that Dr. Cantu surveyed what was, in his view, the "present state" of scientific and medical literature. This process does not result in a testable hypothesis. Those wanting to replicate his methodology have no means of determining: (i) why he considered what he considered; (ii) why he discarded what he did not consider: (iii) how he evaluated whatever it is he considered; and (iv) what process he used to reach his conclusion. The universe of scientific and medical literature is not defined or set forth. What he means by "present state" of the literature is also not defined. Nor does he opine as to why the "present state" of scientific and medical literature is an accurate reflection of the information that was available to Riddell at the time of the challenged advertising claims. Thus, his methodology is inherently subjective.

Dr. Cantu's methodology is further subjective because it is based on his own, undefined criteria and no identifiable factors. Only the UPMC Study and the Wisconsin Study are listed in his documents considered. If Dr. Cantu was truly basing his expert opinion on only those two studies, as one would have to assume based on his report, he would have no choice but to determine that Riddell Revolution Series of football helmets reduce the incidence of concussions. As the UPMC Study supports such a claim and, as this Court found, "nothing in the Wisconsin Study suggests that Riddell misrepresented the results of the UPMC study." Saylor Decl., Ex. 29; Dkt. No. 65 at 30.

Dr. Cantu also notably omits the Virginia Tech Study, which is directly on point to the issue at hand and shows that the UPMC Study *understated* its results. He then supplemented his report with the 2016 Collins Study (which was available before he signed his report). The 2016 Collins Study does not even purport to measure the incidences of concussions. Saylor Decl., Ex. 19. Rather, it measured the characteristics of concussions "severity" and not efficacy of CRT as compared to other modern football helmets. *Id.* One is left guessing as to how Dr. Cantu picked which studies to "consider" to come to his conclusion and why or how one study is better than another. It seems as though Dr. Cantu simply has preconceived notions that football helmets are not the "solution" to concussion prevention and therefore should not be promoted as a solution to concussion reduction. That is a policy preference, not an admissible expert opinion.

Dr. Cantu's universe of scientific and medical literature appears to include the many consensus statements that have been issued on concussions. *See* Saylor Decl., Exs. 18, 19, 20, 22. The consensus statements are omitted from his report, but when asked if they are included in his survey of the scientific and medical literature, Dr. Cantu said "sure." Saylor Decl., Ex. 15 at 157:24-158:7. Those consensus statements have changed over time. They also include findings with which Dr. Cantu does not agree. Yet, he signs his name to them if he agrees with more of the consensus statements than he disagrees with. There is no way to know which parts of the consensus statements he dissents from without asking him. This literature is nebulous and fluctuating, yet it is part of the scientific and medical literature that apparently can be used to show a lack of "support" for an advertising claim. Dr. Cantu makes no effort to explain how these changes from statement to statement on issues relevant to this case affect the state of scientific and medical literature during the actual class period. Nor does he explain how he can

object to a consensus statement but have it published with his name on it, yet this same changing (sometimes wrong) consensus must support Riddell's specific claims made at a specific times.

Dr. Cantu's report also fails to explain his methodology. An expert's report must contain "a complete statements of all opinions the witness will express and the *basis and reasons for them*." Fed. R. Civ. P. 26(a)(2)(B)(i) (emphasis added). Yet Dr. Cantu provides no basis or reasons for the conclusions he provides in his expert report. This is improper. Absent is any explanation for how he arrived at his conclusions, beyond stating that he "surveyed the present state of medical literature, documents relevant to this case, and incorporating [his] over sixty (60) years of experience as a Neurosurgeon." Report at 2.

An expert report must include how and why the expert reached a particular a particular result, not merely a list of the expert's conclusory opinions. *See*, *e.g.*, *Dunkin' Donuts Inc. v.*Patel, 174 F. Supp. 2d 202 (D.N.J. 2001), adopted by, 174 F. Supp. 2d 202, 204 (D.N.J. 2001) (excluding an expert for failing to comply with Rule 26 by failing to set forth the basis and reasons for the opinions included in his memorandum). The Court in *Dunkin'* held:

An expert report under Rule 26 'is intended to set forth the substance of the direct examination of the expert witness,' and must 'disclose the data and other information considered by the expert.' Advisory Committee Notes to the 1993 Amendments to Rule 26. To satisfy the Rule, 'the report must provide the substantive rationale in detail with respect to the basis and reasons for the proffered opinions. It must explain factually why and how the witness has reached them.'

Dunkin' Donuts Inc. v. Patel, 174 F. Supp. 2d 202, 211 (D.N.J. 2001) (quoting Hilt v. SFC, Inc., 170 F.R.D. 182, 185 (D. Kan. 1997). "The purpose of the reports is to avoid the disclosure of 'sketchy and vague' expert information." *Id.* (quoting Sierra Club v. Cedar Point Oil Co., 73 F.3d 546, 571 (5th Cir. 1996). Dr. Cantu's report fails this test.

B. Dr. Cantu's Method Has Not Been Subject To Peer Review.

If Dr. Cantu's methodology cannot be tested or replicated, as discussed above, it is far from meeting the rigorous standard of peer review. However, the UPMC Study was the subject of peer review, which gives less credence to Dr. Cantu's subjective dismissal of the entire study. *See Riddell, Inc. v. Schutt Sports, Inc.*, 724 F. Supp.2d 963, 975 (W.D. Wis. 2010). The consensus statements are part of Dr. Cantu's "present state of the scientific and medical literature." Report at 2; Saylor Decl., Ex. 15, Cantu Dep. at 157:24-158:7. But even if Dr. Cantu does not agree with part of the consensus statements, he signs his name to them. According to Dr. Cantu, as long as he agrees with more of the statements than he disagrees with, it is fine to publish the statement. Saylor Decl., Ex. 15 at 161:23-162:11. There is no way to know which parts of the consensus statements he dissents from without asking him and his process for identifying such disagreements is not set forth in his report. Much of the so-called scientific and medical literature that Dr. Cantu relies on is unreliable in whole or in part, and Dr. Cantu makes no effort to address this failing.

C. Dr. Cantu's Method Has A High Potential Rate of Error.

Not being able to replicate or identify any system whatsoever that was used by Dr. Cantu makes the potential rate of error astronomical. He also is admittedly considering the "present state" of the scientific and medical literature, which is constantly evolving and changing. Report at 2. Whether something is known now in the scientific community about concussions is not a reliable means of assessing what was known during the relevant time period in this matter: 2009 to 2012. Adding anything that occurred after 2012 only adds to the obvious potential for error. Plaintiffs make no effort to explain how a company can be held liable *post hoc* for scientific or medical revelations that were not part of the scientific or medical literature at the time Riddell made marketing claims about CRT.

This point resonates even more in light of the fact that the existing science from a study, such as the UPMC Study, supports the claims at the time they were made. Moreover, the studies that do not even contradict the claims, but may have some relation to concussions and football helmets, such as the 2014 Wisconsin study, had not even been published in the relevant time period. *See* Dkt. No. 65, at 35-37. *See, e.g., Johns v. Bayer Corp.*, Civil No. 09cv1935 AJB (DHB), 2013 WL 1498965, at *17 (S.D. Cal. April 10, 2013) (finding that an expert analysis of studies and evidence from outside the class period is irrelevant). Riddell stopped running the CRT advertisement in 2012, so any "present state" of literature that includes the time period after 2012 is not a reliable standard to use for claims that were not made after 2012. Dr. Cantu has admitted the state of the literature is constantly changing but he includes no explanation about why the state of the literature in 2017 is the same as it was in 2007 through 2012.

D. Dr. Cantu Did Not Utilize His Own Existing Standards When Giving His Opinion in this Matter

Dr. Cantu's own methodology proves that Riddell properly relied on the UPMC Study in 2008 and through 2012. Dr. Cantu's contribution to the state of the literature on the topic of neck strength proves just that. The UPMC Study was the only study of its kind regarding CRT when Riddell made the CRT claims. One study is sufficient support in Dr. Cantu's world to support a claim on concussion reduction. This is true even if the claim is new and runs counter to previously held beliefs.

For example, in 2012, Dr. Cantu signed his name to a statement that "no evidence was provided to suggest an association between neck strength increases and concussion risk reduction." Saylor Decl., Ex. 20, Cantu Dep., Ex. 18, Consensus Statement from Zurich 2012. In 2014, merely two years later, he published a study that showed such an association. Report Ex. A at 25. In 2016, another two years later, he published an article that his finding that association

was Gospel, claiming "[w]e recently concluded a study that showed that athletes with the greatest neck strength had the fewest concussions, and those with the least had the highest number of concussions. (Collins et al. 2014)." Saylor Decl., Ex. 21. Therefore, following Dr. Cantu's own existing standards, it is perfectly acceptable to issue a finding attributing concussion reduction attributes to a studied concept (CRT or neck strength) after completing only one study (UPMC or Dr. Cantu's) in support of those attributes.

Moreover, Dr. Cantu's 2016 article is all the more extraordinary, because he had signed his name to medical and scientific literature just four years earlier that rejected the association between neck strength and concussions due to lack of evidence. So Dr. Cantu can move from signing his name to statement claiming a lack of evidence on neck strength and concussion to being completely confident that neck strength does reduce the risk of concussion after one study. That is fine for Dr. Cantu, but not when he is paid to advocate against Riddell, in which case Dr. Cantu can imply that Riddell acted improperly, even if such an implication is contrary to his own practice (and contrary to statements from NOCSAE, the industry standard setter, of which he is a member).³

³

Dr. Cantu signed a conflict of interest agreement with NOCSAE. He agreed to avoid the appearance of impropriety. He is now taking a \$25,000 retainer from Plaintiffs to testify against a NOCSAE licensee—Riddell. In doing so he is rejecting a NOCSAE publication asserting that helmets that pass its laboratory tests do provide for protection against concussion. Saylor Decl., Ex. 15, Cantu Dep. at 47:6-48:2. That creates more than an "appearance of impropriety." Moreover, Dr. Cantu's CV contained as "submitted for publication" an article on defining concussion. That is a directly on point topic, but when asked to produce the article, Plaintiffs revised his Rule 26 disclosure the day before his deposition, and removed any reference to that article. Dr. Cantu's ubiquity of positions both for and against propositions at issue in this case cast further serious doubt on his reliability as well as the reliability of his opinions.

E. Dr. Cantu's Method Is Not Generally Accepted, or Even Consistently Utilized By Dr. Cantu

As mentioned above, Dr. Cantu did not implement his own techniques for coming to a conclusion when he gave his opinion in this matter. There is no evidence that, when producing a conclusion about the current state of the scientific and medical literature, he applied any filtering criterion. He also testified at his deposition that he did not include the current standards for helmets issued by the NOCSAE, an organization in which he holds the position of Vice President. Saylor Decl., Ex. 15 at 46:25-47:13. In fact, during his deposition he admitted that he did not even know that the NOCSAE website says that a helmet certified to a NOCSAE standard provides a substantial level of protection for serious head injuries, including concussions. *Id.* at 47:6-25.

Finally, as mentioned above, he did not list the consensus statements as part of the world of documents he considered, but flippantly said they were indeed to be included in what he calls the present state of scientific and medical literature. Dr. Cantu requires some fuzzy level of substantiation from Riddell when he says there is "no reliable evidence" to support Riddell's claims (despite the UPMC and Virginia Tech studies and the statement by NOCSAE), but does not apply that level of scrutiny to his own broad conclusions (many of which he retracted or distanced himself from in his deposition).

F. There Is No Relationship Between Dr. Cantu's Methodology And That Which Has Been Established To Be Reliable

As discussed above, Dr. Cantu's own actions demonstrate what proper scientific method to follow when exploring an advancement in the study of concussions in football. Proper method is to conduct a study, as he did for neck strength, and then tout its results. Riddell did just that with the UPMC Study. Dr. Cantu now criticizes Riddell, for doing the same with respect to

CRT. This proves that Dr. Cantu is employing an entirely subjective double standard. Dr. Cantu also ignores the Virginia Tech Study, but includes the 2016 Collins Study as part of his "present state of medical literature." The 2016 Collins Study is off point, while the Virginia Tech Study is directly on point. Once again, there is no way to determine what method Dr. Cantu used to determine what he considered and why (or why not) one study is included and another is not or why one outranks another. Such arbitrary decisions are not reliable or testable.

G. Dr. Cantu's Methodology is Not Consistent With The Non-Judicial Uses

Dr. Cantu's conclusions, without support or explanation, would not be considered in the non-judicial community because it is merely a stream of inchoate concepts set forth in bullet points, sandwiched between conclusions that do not 'move the ball.'

Based on the *In Re Paoli* Factors, Dr. Cantu's testimony and report should be excluded as unreliable. In *Wolfson-Verrichia Group, Inc.*, the Court excluded the Plaintiff's expert as unreliable, finding that "[t]he principal problem underlying [the expert's] analysis is that there is no meaningful explanation as to how it was performed. Instead, [the expert] stated that he reached his opinions by deliberating upon the evidence, and interpreting it in light of his experience..." *Wolfson-Verrichia Grp., Inc. v. Metro Commer. Real Estate, Inc.*, Civil Action No. 5:08-cv-4997, 2013 WL 1286184, at *11 (E.D. Pa. March 28, 2013). Likewise, Dr. Cantu's testimony should be excluded because there is no meaningful explanation as to how his analysis was performed, other than interpreting what Dr. Cantu views as the evidence in light of his experience, and it fails seven of the *In Re Paoli* factors. "[W]ithout a reliable method, result-oriented 'judgment' cannot be distinguished from scientifically or methodologically-based judgment." *Magistrini v. One House Martinizing Dry Cleaning*, 180 F. Supp.2d 584, 606

(D.N.J. 2002), *aff'd* 68 Fed. Appx. 356 (3d Cir. 2003). Here, Dr. Cantu's analysis is result oriented and totally subjective. It should be excluded.

Likewise, his conclusions do not touch on the issue at hand in this matter, which is not whether the tests that measure the efficacy of CRT are reliable (the UPMC Study has already been found to be reliable), but whether Plaintiffs can support a claim that the Riddell Revolution series of helmets are not better at reducing the risk of concussions than other helmets on the market. Dr. Cantu does not opine as to whether the Riddell Revolution series of helmets are better (or worse) than any other modern helmet available on the market. Rather, he concludes, "I believe that a helmet does even in the sport of football produce some protection for a concussion, but I do not believe that there is any *definitive literature* that tells me what the incidence would be." Saylor Decl., Ex. 15 at 94:5-10 (emphasis added). So, Dr. Cantu relies upon a preponderance of the evidence when it suits Plaintiffs, but requires definitive literature to support Riddell. Dr. Cantu does not explain the difference between his "definitive literature" standards and his preponderance of the evidence standard.

Moreover, Dr. Cantu has merely determined that he does not believe the amount of concussion reduction attributable to a football helmet is measurable. That is not the issue before the Court. The issue is can Plaintiffs support their claim that Riddell is not "better" than any other helmet on the market. Dr. Cantu does not know. The UPMC Study says they are better than traditional helmets (as does Virginia Tech). In the face of Dr. Cantu's equivocation, the UPMC Study would more than satisfy a preponderance of the evidence (as would the Virginia Tech Study). Surprisingly, Dr. Cantu admitted that he did not actually examine the helmets at issue in this case. Saylor Decl., Ex. 15 at 64:20-65:3. His opinion should be excluded. *See*

Neale, 2013 WL 784962, at *3 (expert excluded for not examining the facts of the case before him).

II. DR. CANTU'S TESTIMONY SHOULD BE EXCLUDED BECAUSE IT IS NOT RELEVANT TO THE CASE

The third factor that Courts consider when evaluating whether an expert should testify is relevance. *Daubert*, 509 U.S. at 589. An expert's testimony must "aid the jury in resolving a factual dispute." *Lauria v. Amtrak*, 145 F.3d 593, 599 (3d Cir. 1998) (quoting *Daubert*, 509 U.S. at 591). This element imposes on the Court to determine "whether the expert testimony proffered is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *United States v. Schiff*, 602 F.3d 152, 173 (3d Cir. 2010). The standard associated with the relevance analysis "is met when there is a clear 'fit' connecting the issue in the case with the expert's opinion that it will aid the jury in determining an issue in the case." *Meadows v. Anchor Longwall & Rebuild, Inc.*, 306 Fed. Appx. 781, 790 (3d Cir. 2009) (internal citations omitted). "Fit" asks whether there is a sufficient connection 'between the expert's testimony and the facts that the jury is being asked to consider." *Wolfson-Verrichia Grp., Inc.*, 2013 WL 1286184, at *11 (quoting *United States v. Schiff*, 602 F.3d 152, 172-73 (3d Cir. 2010)).

Dr. Cantu's testimony does not fit the facts that the jury is being asked to consider. A fact finder will not be asked to consider whether Riddell made a false statement about the measurability of CRT's benefits in relation to no protection or a stated level of protection.

Instead, Plaintiffs' remaining claims in this case are about CRT in relation to other helmets on the market. Dr. Cantu's purported testimony that the concussion reduction attributes of CRT cannot be accurately measured, would serve only to confuse the issues and mislead the jury.

This is particularly true in light of the fact that Plaintiffs cannot challenge that the UPMC Study did find it measurable in relation to traditional helmets. The Court has also already ruled that the

UPMC Study is a reliable study, and that the Wisconsin study does not negate the findings of the UPMC Study. Saylor Decl., Ex. 28; Dkt. No. 65, at 30. Allowing testimony that is contrary to the law of the case does not "fit" the issues that the jury will be asked to decide.

The Court must decide if the expert's testimony reliably "fits" the case, which it does not. *In re Front Loading Washing Mach. Class Action Litig.*, No. 08-51 (FSH), 2013 WL 3466821, at *2 (D.N.J. July 10, 2013). "It is common ground that a trial court may bar expert testimony if that testimony will not assist the jury to sort out contested issues." *U.S. v. Mehanna*, 735 F.3d 32, 79 (1st Cir. 2013).

As this Court and others have recognized, identifying flaws in a scientific study does not necessarily make marketing statements based on such a study false or misleading. See *Gaul v. Bayer Healthcare LLC*, 2013 U.S. Dist. LEXIS 188951, at *4 (D.N.J. June 19, 2013) (finding that marketing statements based on an allegedly unreliable study tended to prove that such statements were unsupported, "but not that they are false"); *Scheuerman v. Nestle Healthcare Nutrition, Inc.*, Civ. 10-3684 (FSH), 2012 WL 2916827, at *7 (D.N.J. July 17, 2012) ("At best, Plaintiffs can prove that Nestle's studies were not sufficiently strong; while this may be enough to make out an ordinary claim not premised on a theory of fraud, it is insufficient to demonstrate entitlement to relief under" the consumer protection laws of New Jersey). *See also Adamson v. Ortho-McNeil Pharm., Inc.*, 463 F. Supp. 2d 496, 503 (D.N.J. 2006) (finding that marketing statements were accurate and therefore not misleading or deceptive).

In order for Plaintiffs to succeed on their false advertising claim, they will need to provide evidence that shows the Riddell Revolution series of helmets are not better at reducing concussions than any other helmet. They will not be able to meet their burden with an expert who believes that helmets do reduce the incidence of concussions but the exact amount of that

reduction simply cannot be measured. A false advertising claim cannot be proven when a

Plaintiff cannot even decide whether the challenged claim is true or false. See Scheuerman v.

Nestle Healthcare Nutrition, Inc., Civ. 10-3684 (FSH), 2012 WL 2916827, at *7 (D.N.J. July 17,

2012) ("At best, Plaintiffs can prove that Nestle's studies were not sufficiently strong; while this

may be enough to make out an ordinary claim not premised on a theory of fraud, it is insufficient

to demonstrate entitlement to relief under" the consumer protection laws of New Jersey). Dr.

Cantu's testimony does not aid Plaintiffs in pursuing their false advertising claim and will not aid

the jury in reaching a verdict because his testimony is not relevant. Accordingly, Dr. Cantu's

testimony and report should be excluded.

CONCLUSION

For all of the reasons set forth above, Riddell respectfully requests that the Court grant

the Motion in its entirety, and grant such other and further relief as the Court deems just and

proper.

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Respectfully submitted,

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